UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Michelle Simha, as Trustee for the Next-of-Kin of Noah Leopold, Plaintiff, vs. Mayo Clinic, Defendant.	Civil File No. 24-CV-01097-DTS **MAYO CLINIC'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO AMEND TO ADD A CLAIM FOR PUNITIVE DAMAGES**

Noah Leopold's death in September 2023 was a tragedy. Mayo Clinic ("Mayo") sympathizes with Leopold's family and deeply respects the difficulty of losing a loved one. Mayo understands Leopold's family has questions regarding the care provided, and Mayo understands that Plaintiff was entitled to initiate this lawsuit. Plaintiff may pursue her theories of liability, just as Mayo will seek to establish that the care it provided was, in all respects, consistent with applicable standards of care.

What Mayo cannot countenance is Plaintiff's attempt to distort the evidence to manufacture a claim for punitive damages. Leopold tragically died, despite the best efforts of his care providers at Mayo, because of an unforeseen and unforeseeable surgical complication—a complication that to Mayo's knowledge has never been reported in the medical literature, and the cause of which remains unknown to this day. The argument that Mayo providers somehow "deliberately disregarded" Leopold's rights or safety, after a decade of careful treatment for advanced heart failure, because of this unforeseeable

complication is untenable—particularly where, as here, the patient was in danger of dying within days or weeks if he did not receive a new heart, where the surgery was highly complex, and where adverse outcomes, including death, unfortunately do occur despite the best care.

After nine depositions of Mayo providers and production of thousands of pages of documents, Plaintiff has utterly failed to identify for this Court any record evidence of bad faith, maliciousness, or egregious misconduct, as is required to seek punitive damages. Instead, Plaintiff has resorted to misstatements of the law, misguided and unsupported accusations regarding the relevant medicine, outright misrepresentations of the record, and inflammatory arguments of counsel.

There is no sound basis in the law or the factual record before this Court to permit Plaintiff to assert a claim for punitive damages against Mayo. As detailed below, Plaintiff's allegations and evidence fall far short of the exacting standard required to pursue such a claim, which requires a prima facie showing, by clear and convincing evidence, that Mayo acted with "deliberate disregard" for Leopold's rights or safety.

First, Plaintiff's bid for punitive damages fails at the outset because Plaintiff offers no expert testimony to establish essential elements of each of her underlying causes of action, including the essential element of causation. Absent such evidence in this case, which involves disputed issues of complex medical practice, Plaintiff cannot even establish that Mayo negligently caused Leopold's death—much less establish by clear and convincing evidence that Mayo acted with deliberate disregard.

Second, the Court's independent review of the whole record will show that Plaintiff's allegations and characterizations of the evidence are all either demonstrably false or insufficient to support a punitive damages claim. Plaintiff claims Mayo wrongfully withheld information about the health history of Leopold's donor, but offers no evidence that the undisclosed factors were clinically relevant to Leopold's care, were risks that should have been disclosed under the objective "reasonable person" standard that governs negligent nondisclosure under Minnesota law, or causally contributed in any way to Leopold's injury. Moreover, Plaintiff's own allegations establish not that Mayo "concealed" information about the donor from Leopold, but that Mayo openly advised Leopold that Mayo could not share this information. Knowing he could not have answers to these questions, he consented to proceed with surgery. Twice.

Similarly, Plaintiff goes to great lengths to generate the illusion that the OCS Heart device used to transport the donor heart carried unusual risks that should have been disclosed to Leopold. In reality, there is no dispute that the Mayo team used this FDA-approved device for its approved purpose, and the most current clinical data confirm this device does not entail any risk of adverse outcomes materially different from the alternative method of transporting a donor heart on ice.

In short, and as fully detailed below, the Court need only review the record evidence for itself to see that Plaintiff's bid for punitive damages fails on the facts.

In the end, Plaintiff fails to cite a single reported case, in Minnesota or any other jurisdiction, in which a court permitted a claim for punitive damages on facts remotely similar to this case. That is no accident. This is not a punitive damages case. Plaintiff may disagree or remain dissatisfied with the realities of the organ donation and transplantation system at Mayo and elsewhere, and she may argue that Mayo was negligent or should have provided more information to Leopold about the donor or the OCS Heart device. But there can be no credible dispute that Leopold's Mayo providers followed their training, experience, and clinical practice in rendering the care at issue in this case. The actual evidence—the sole focus of this Court's review—is unmistakable; this is not a punitive damages case. The Court should deny Plaintiff's motion.

FACTUAL AND PROCEDURAL BACKGROUND

I. Noah Leopold's Care and Treatment at Mayo Clinic

A. History of Leopold's Treatment at Mayo and Admission for Transplantation in August 2023

Noah Leopold was in end-stage heart failure when he was admitted to Mayo Clinic in August 2023 to undergo heart transplantation surgery. Declaration of Nathan J. Ebnet in Opposition to Plaintiff's Motion to Amend to Add a Claim for Punitive Damages ("Ebnet Decl.") [redacted] [redacted] Leopold's heart failure resulted from use of Adriamycin, a chemotherapy drug administered to Leopold (by a non-Mayo facility) to treat cancer when he was approximately seven years old. *Id*.

[redacted]

[redacted]

Leopold showed some clinical improvement over the course of his initial encounters at Mayo in 2014. [redacted] Leopold continued to be followed and evaluated annually by Mayo's transplant team, and remained relatively stable for several years.

Leopold's condition began to deteriorate around late 2022 and early 2023, when he developed atrial fibrillation and required placement of a pacemaker, leading him to return to Mayo for further evaluation. [redacted]

[redacted] According to Leopold's father, Norman Leopold, the family asked Dr. Spencer "specific questions as to what the procedure would involve." Declaration of Norman Leopold, ECF No. 32, ¶ 6. Norman Leopold and Leopold also asked "many questions . . . regarding the donor," including questions "about the donor's medical history, drug use, age, and location." *Id.* In response, "***Dr. Spencer said he was not allowed to disclose any such information.***" *Id.* (emphasis added). [redacted]

[1] An IABP is a mechanical device that assists the patient's heart in pumping. Leopold's heart failure was so severe, in other words, that his heart was incapable of pumping sufficient blood on its own to maintain organ function. Plaintiff asserts that "[t]hough he needed a heart transplant, [Leopold's] underlying health was good." Pl. Mem. 3. [redacted]

[redacted]

After he consented, Leopold's clinical status worsened. [redacted]

B. The August 29 Donor Heart

Leopold received another offer of a donor heart on August 29, 2023 (referred to as the "August 29 Donor Heart"). As he had done on August 17, Leopold consented to proceed with the transplantation after further discussion with Mayo cardiologist Dr. Drew Rosenbaum. [redacted] ECF No. 32, ¶ 7I. Leopold also met with Dr. Mauricio Villavicencio, the cardiovascular surgeon scheduled to perform the operation. ECF No. 32, ¶ 8.

In accordance with standard practice, Dr. Villavicencio assessed an array of information about the August 29 Donor Heart to determine it was suitable for Leopold. This included background information about the donor's social and health history that Plaintiff exclusively emphasizes in her motion. Of far more clinical importance, Dr. Villavicencio also reviewed multiple sophisticated diagnostic studies that directly measured the health and function of the donor's heart. These included a CT scan and x-ray of the chest, electrocardiogram, echocardiogram of the heart, and coronary angiography. *See* Declaration of Brandon Thompson ("Thompson Decl."), ECF 28, Ex. K at 0042-44. [redacted]

[redacted]

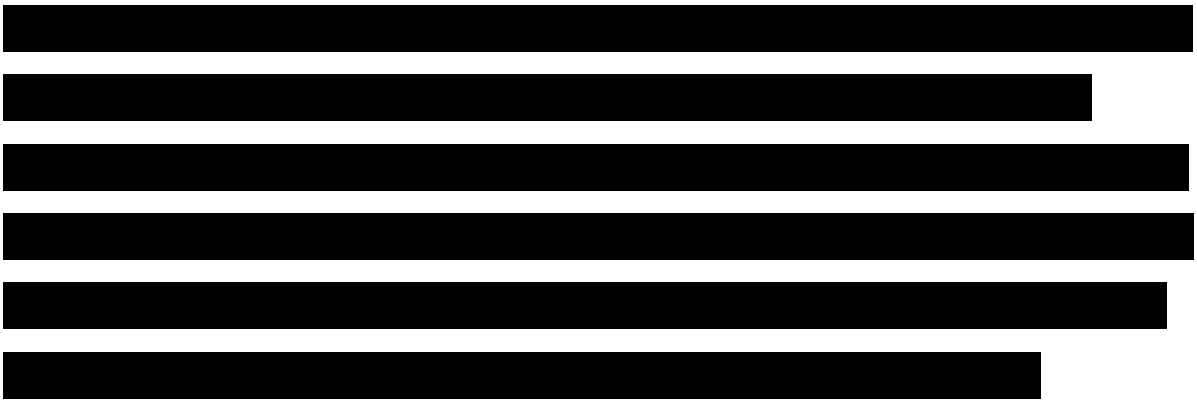
[2] Plaintiff complains that "[n]o one from Mayo had done anything to calculate whether there would be a size mismatch, even though UNOS provides a calculator allowing doctors to do exactly that." Pl. Mem. 22-23. [redacted]

The August 29 Donor Heart was a "meets-risk-criteria" donor heart. [redacted] Having received extensive education and counseling from the Mayo transplant team throughout his decade of treatment, Leopold was well aware of these definitions, their implications regarding the donor's history, and attendant risks and benefits. [redacted][3]

C. Procurement and Transit of the August 29 Donor Heart via the OCS Heart Device

[redacted]

[3] Leopold's fully-informed express consent to receive a heart from a "meets-risk-criteria" donor definitively disproves Plaintiff's contention that he would not have consented to receive "the heart of a drug addict, criminal, or someone with a troubled history." Pl. Mem. 18. That phrase colloquially captures the very definition of this donor pool, which Leopold plainly understood.



Real-time in-transit monitoring of these objective measures is made possible by the OCS Heart device, an FDA-approved device used by Mayo and other transplant centers to preserve donor hearts if certain factors are met, such as an extended distance between the donor organ and Mayo. *Id.* Ex. F at 10. The device is one of several new technologies that allow donor hearts to be transported longer distances, over longer periods of time. The "traditional" method of transporting donor hearts before the advent of such technologies was simply to put the heart on ice in a cooler and transport it to the recipient as quickly as possible. But the traditional method of "[c]old static storage of the donor's heart for more than four hours leads to significant ischemic injury to the heart, which limits the duration of safe preservation, and distance of procurement." *Id.* Ex. Q at 2. In contrast to the traditional cold storage method, "OCS keeps the heart perfused [with blood] close to the physiological state beyond the four hours with superior results, which allows [transplant teams] to travel further and longer distances, leading to expansion in the donor pool." *Id.* The OCS Heart device also allows for "continuous monitoring of aortic pressure, lactate level, and coronary blood flow" of the donor heart, which allows the

procurement team to monitor the status of the heart in transit and watch for signs of potential tissue damage, such as rising lactate levels. *Id.*

All available evidence, including the physiologic data from the OCS Heart device, confirms that the August 29 Donor Heart remained in normal condition and suitable for transplantation throughout its transit to Mayo. *Id.* Ex. X at 123:16-20 ("I feel that everything from that run, from the time we got [the heart] on to [the OCS device] to the time it came off, it looked good. I had no concerns."); Ex. T at 24:13-15 ("[T]he lactates were excellent.").

D. The Transplantation Surgery

The transplantation surgery was performed by Dr. Villavicencio. When Dr. Villavicencio inspected the August 29 Donor Heart in the operating room, it had "[e]xcellent function." *Id.* Ex. T at 39:2-3. The heart showed some limited bruising, but this was entirely normal—approximately 90% of hearts transported on the OCS Heart device show some bruising of this nature. *Id.* at 80:8-21.

[redacted]

[redacted]

The cause of the complication with the August 29 Donor Heart remains unknown. The complication was something Dr. Villavicencio had "never seen" before. Thompson Decl. Ex. T at 89:14-18. In retrospect, Dr. Villavicencio testified, his best "hypothesis" is that "microtears on the aortic root" caused blood to "infiltrate[] the heart and make it bleed from everywhere." *Id.* at 79:1-9. But that is only a hypothesis. The fact remains that Dr. Villavicencio unequivocally testified: "I don't know . . . why it bled from everywhere." *Id.* at 79:8-9. And he was equally clear that—whatever the cause of the complication—it could only potentially be understood "[i]n hindsight," and was *not* something that could have been identified prior to transplantation "with our current methods of diagnosis." *Id.* at 94:9-23.

Following the complication, Leopold was placed on cardiovascular support, transferred to the ICU, and promptly re-listed for transplant following neurologic evaluation. He underwent multiple subsequent procedures in the OR for exploration and chest washout. Another suitable donor heart became available and was successfully transplanted on September 7, 2023. Unfortunately, on the morning of September 8, Leopold was found to have fixed and dilated pupils, prompting a head CT and neurologic evaluation. Imaging showed extensive intracranial hemorrhage and diffuse cerebral edema. There was no medical or surgical intervention that could reverse these intracranial sequelae. Support was withdrawn, and Leopold passed on September 9. [redacted]

II. Plaintiff's Purported Facts in Support of Her Motion

Plaintiff's characterizations of the evidentiary record and applicable medical standards range from misleading to demonstrably false. To put Plaintiff's allegations in context and direct the Court to the actual *evidence* it may consider—as opposed to the mischaracterizations and arguments of counsel—Mayo responds here to the "Factual Background" section of Plaintiff's memorandum, which, in reality, is "argument dressed up as factual averment." *Njema v. Wells Fargo Bank, N.A.*, 2014 U.S. Dist. LEXIS 206126, at *36-*38 (D. Minn. Nov. 4, 2014).

A. Plaintiff's False Allegations Regarding Mayo's Promises to Leopold

Plaintiff claims throughout her memorandum that Mayo made an "explicit promise to [Leopold] that it wouldn't accept the heart of a donor who had died of a drug overdose." *See, e.g.*, Pl. Mem. 1, 18, 29-30. This claim is demonstrably false.

Just prior to the planned August 17 transplant that was subsequently deferred, Leopold and his father met with Dr. Bradley Ternus, a Mayo physician in the cardiac intensive care unit. ECF No. 32, ¶ 4. Dr. Ternus specializes in cardiac critical care—not transplantation. For Leopold specifically and transplant patients more generally, Dr. Ternus is not involved in any of the decisions about

which organs to take once an organ offer has been made. [redacted][4]

[redacted]

The Court need only review Dr. Ternus's actual words—rather than Plaintiff's self-serving characterization of them—to see that this was not an "explicit promise" to Leopold regarding donors that died from drug overdose. Instead, it was a statement about donors considered high risk for transmissible viral disease, which would typically include, but not be limited to, donors who had died of a drug overdose. Leopold understood that; his father understood that; they had been educated about it for a decade; and Leopold consented to it. Plaintiff's attempt to twist Dr. Ternus's words into a supposed promise that

[4] Pursuant to Mayo's motion for sanctions, ECF No. 37, Mayo is seeking to exclude Dr. Ternus's deposition testimony from further use in this case. Mayo refers to it here for the sole purpose of demonstrating that Dr. Ternus's testimony, and the August 2023 video recording of him that was played during his deposition, do not support Plaintiff's motion.

Mayo "would not accept a heart from a drug overdose donor without having a conversation with him about it first," Pl. Mem. 18, is unavailing. What Dr. Ternus told Leopold was that Mayo would not accept a heart from a "*high risk*" donor, as defined by Public Health Service guidance, without a conversation—and Mayo did exactly that.

[redacted][5]

B. Plaintiff's False Allegations Regarding Procurement of the Donor Heart

Plaintiff takes extraordinary liberties with the factual record in an attempt to generate the false impression that the Mayo perfusionists who monitored the OCS Heart device and the August 29 Donor Heart in transit noticed concerning findings that were not reported to the surgeons. In particular, Plaintiff alleges that the Mayo perfusionists were concerned [redacted] Pl. Mem. 2. [redacted]

[5] Plaintiff's allegations regarding supposed risks associated with organs from donors with a history of drug use or drug overdose belies ignorance of the realities of the organ transplant system in the United States. According to testimony in this case, 20-30% of donations come from donors who died of drug overdoses. Thompson Decl. Ex. T at 54:22-25. The American Heart Association trumpets clinical research indicating that "[s]urvival rates after a heart transplant are unaffected if the organ donor had used illicit drugs or died due to an overdose." *See* https://newsroom.heart.org/news/hearts-from-donors-who-used-illicit-drugs-or-overdosed-safe-for-transplant-cuts-wait-time.

[redacted]

At the threshold, Plaintiff's argument is based on a flagrant misrepresentation of the documentary evidence. Plaintiff asserts throughout her brief that a Mayo perfusionist noticed the heart was "not robust" and "not happy," but did not report this to anyone. *E.g.*, Pl. Mem. 44. These allegations arise from text messages sent by Danielle Fay, one of the Mayo perfusionists, shortly after she learned of the complication that occurred in Leopold's surgery. [redacted] Contrary to Plaintiff's argument that these were concerning findings Ms. Fay failed to report, Ms. Fay unequivocally testified that these were simply not concerning findings—they were well within the range of normal presentation of hearts on the OCS Heart device. *Id.* Ex Z at 27:7-10 ("There is a wide range of how robust hearts are when they're on the machine. As to if there is anything specific about the heart that stands out to me, no."); *id.* 28:6-9 ("There is a wide range of what is normal on the machine. Some are very robust, some are not, and it doesn't indicate how the heart's going to do off the machine."); *id.* 38:13-14 (explaining that virtually all OCS hearts are not "happy" during the short car rides between airport and hospital, as the "bumps of the vehicle the hearts do not always like, and that's normal.").

In reality, the August 29 Donor Heart was "excellent by the criteria of the International Society of Heart and Lung Transplantation. . . . It checked all the boxes for an optimal, excellent heart." *Id.* Ex. T at 114:11-15. It was that way when it was procured from the donor, during transit, and upon arrival to the operating room.

C. Plaintiff's Inaccurate Allegations Regarding the OCS Heart Device

Plaintiff claims there are questions regarding the safety of the OCS Heart device, particularly as compared to traditional cold transit. Pl. Mem. 6-11. Plaintiff references three studies conducted in connection with FDA approval of the device, and asserts that the PROCEED II study "is the only study comparing OCS to standard cold storage." *Id.* at 7. Plaintiff states that researchers found overall survival was lower if a donor heart was preserved on the OCS machine. *Id.* at 7. Plaintiff implies that the purported risks identified by these studies continue to apply to current clinical practice. *Id.* at 6-11. And Plaintiff asserts that Mayo "misleads patients about the . . . efficacy of the OCS." *Id.* at 10. Based on these assertions, Plaintiff argues that Leopold "had a right to know about the risks associated with using the OCS Heart" and "Mayo deliberately deprived him of that right." *Id.* at 32-33.

Plaintiff's assertions regarding the risks associated with the OCS Heart device are inaccurate and do not reflect current medical research and clinical realities. Indeed, Plaintiff's allegations do not even accurately reflect the OCS documentation upon which Plaintiff herself relies.

At the threshold, it is critical for the Court to understand that the PROCEED II trial, the core of Plaintiff's allegations and arguments, is the oldest dataset among relevant information about the device. The OCS Manual

characterizes the PROCEED II trial as "historical," and specifies that it was "conducted between 2008-2013," using an older version of the device. Thompson Decl. Ex. F at 11. In other words, the data from that study were *a decade old* by the time Leopold was listed for transplant in August 2023. Even so, contrary to Plaintiff's intimations, the fundamental conclusion of the PROCEED II trial was to find that "the clinical outcomes of donor hearts adequately preserved with the [OCS Heart] platform are non-inferior to the outcomes of those preserved with standard cold storage." Ebnet Decl. Ex. C.[6]

More recent studies, including studies detailed in the same OCS Manual from which Plaintiff cherry-picks misleading passages about supposed risks, have continued to confirm that the OCS Heart device is *not* materially riskier than traditional cold storage from a clinical perspective. *See* Thompson Decl. Ex. F at 106-21 (detailing findings in OCS DCD Heart Trial that 6-month survival rate of recipients of OCS hearts were "statistically non-inferior to that . . . in recipients of a DBD donor heart preserved using SOC cold storage"); *id.* at 123-45 (discussing findings in OCS Heart EXPAND and EXPAND CAP trials, which "provide evidence of the effectiveness, safety and favorable benefit/risk profile of the OCS Heart System," including "an overall safety profile that was consistent with routine heart transplantation").

The OCS "Patient Information" guide Plaintiff herself cites makes all of the foregoing absolutely clear. It explains that the PROCEED II trial, which was "designed in 2006," "was an older trial, and there were differences in the design

[6] This Court may refer to the clinical studies embraced by Plaintiff's allegations and arguments. *See, e.g.*, *In re Bair Hugger*, 2017 U.S. Dist. LEXIS 193938, at *22-*23 (D. Minn. July 27, 2017).

of the device and in the techniques used after the donor heart was removed from the OCS Heart System compared to" subsequent studies. Thompson Decl. Ex. G at 8. Even so, the "PROCEED II trial met its primary endpoint and showed statistical non-inferiority to standard of care donor hearts preserved using cold storage." *Id.* The guide goes on to explain that although one follow-up study showed "lower overall survival for the OCS patients compared to the control patients," critically, "***the number of patients who died for reasons related to their heart graft was the same for the two groups***." *Id.* (emphasis added). "This is the only study that reported decreased patient survival following the use of the OCS Heart System and this finding was not observed in other long-term studies of the OCS Heart System performed outside the U.S. and published in peer-reviewed journals." *Id.*

Newer research published on June 8, 2023—i.e., two months before Leopold's heart transplantation surgery—indicates that survival after transplantation with a donor heart preserved by the OCS machine is "noninferior" to survival after transplantation of a donor heart that had been preserved with the use of cold storage. Ebnet Decl. Ex. D at 2130. Mayo was aware of this research at the time of Leopold's transplantation surgery and understood that "OCS has equivalent outcomes" compared to cold storage. Thompson Decl. Ex. V at 14:8-18.

In sum, the older clinical study data discussed in the OCS Manual does not accurately reflect the most current experience and research on the device, including updated safety findings. This is why physicians, including the Mayo physicians at issue here, do not robotically review the manufacturer's

instructions, including all their outdated details, with a patient like Leopold. As Dr. Boilson explained, "a manufacturer's instructions are not clinical guidelines," and physicians' counseling of patients needs to focus on "what the clinical experience is." *Id.* Ex. W at 33:9-11, 36:1-2.

D. Plaintiff's Claim that "One-in-Six" Hearts Preserved Using the OCS Heart Machine are Discarded

Plaintiff claims the OCS Heart Manual indicates that "16%, or nearly one out of every six hearts preserved using OCS [] had to be discarded once they came out of the machine and were inspected," Pl. Mem. 8, and uses this misunderstanding of the clinical study data to argue that there was a "one-in-six chance that [the August 29 Donor Heart] would have to be discarded once it was inspected in the operating room." *Id.* at 19. Plaintiff argues that Mayo failed to disclose this purported risk, *see id.*, and further, that the August 29 Donor Heart was "one of the one-in-six that failed," *id.* at 3. These allegations are demonstrably false.

The OCS Heart Manual identifies four specific reasons that certain donor hearts in the EXPAND and EXPAND CAP trials did not meet transplantability criteria and had to be discarded: (1) continuous rising lactate and final lactate greater than or equal to 5 mmol/L; (2) continuous rising lactate; (3) continuing rising lactate and RV dysfunction; and (4) continuous rising lactate and inability to wean off pacing. Thompson Decl. Ex. F at 129, Fig. 65. Two critical facts demonstrate why Plaintiff's misleading "analysis" of these statistics is irrelevant to this motion.

First, the specific problems that led researchers to discard these hearts during the clinical trials—particularly rising lactate levels—are problems the

OCS Heart device actually reveals during transit through its continuous monitoring of the heart. If a heart demonstrates continuously rising lactate levels, that concern is not first revealed to the surgeon upon inspection "in the operating room," as Plaintiff falsely suggests. It is revealed during transit, and allows the team to reject a heart that is showing signs of injury *before* taking any irreversible steps in operating on the recipient.[7]

Second, none of these factors were present in the August 29 Donor Heart, meaning they are irrelevant to this case. The Mayo procurement team continuously monitored the August 29 Donor Heart's lactate levels and other perfusion parameters during transit, and the "lactates were excellent." Thompson Decl. Ex. T at 24:14-15; Ex. Z at 51:12-22 (confirming lactates and "all of the objective data" from the OCS Heart machine in transit "look[ed] really good");

In short, Mayo's assessment and continuous monitoring of the August 29 Donor Heart proved it was *not* like the hearts that needed to be discarded during the clinical studies—by all objective measures it remained suitable throughout transit and up through transplantation. Plaintiff's contention that Dr. Villavicencio merely had to "hope" that the August 29 Donor Heart "wasn't one of the one-in-six that failed" is simply false. Pl. Mem. 2-3.

[7] *See* Ebnet Decl. Ex. C ("It is . . . possible that the Organ Care System platform might have been able to uncover pathological findings in donor hearts that would have been otherwise acceptable by present standards.").

E. Plaintiff's False Allegations Regarding Mayo's Purported Concealment of These Events

Plaintiff claims Mayo concealed the events at issue in this case, has not reported them to Transmedics—the manufacturer of the OCS Heart device—or the FDA, and has blocked its own doctors from publishing a case report, all in an effort to avoid bad publicity and protect its reputation. Pl. Mem. 24-25. These accusations are false.

Dr. Villavicencio, the surgeon who performed both of Leopold's heart transplantation surgeries, testified that the events of this case went through Mayo's standard morbidity & mortality review process. Thompson Decl. Ex. T at 126:2-6. He relies on Mayo's compliance personnel to make reports to the FDA, if necessary. *Id*. at 126:8-17. Plaintiff has proffered no evidence, and there is none, that Mayo's compliance personnel determined that a report the FDA was necessary, but were dissuaded from making a report.

Moreover, Mayo did not have a legal obligation to report this event to the FDA as a device failure, because Mayo does not have a scientifically reliable basis to believe the OCS Heart caused the complication. *Id.* at 79:8-9 ("I don't know . . . why [the August 29 Donor Heart] bled from everywhere."). The applicable regulation defines a reportable event in this context as "an event that user facilities became aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.3(o). This event does not meet that threshold.[8]

[8] For purposes of this motion, it matters not whether Plaintiff may disagree with Mayo's interpretation of the regulation. Mayo's good-faith belief that this event was not reportable belies Plaintiff's concealment accusations.

With respect to Transmedics, Dr. Villavicencio testified that outcome data from this case was shared with them as part of the ongoing post-approval studies of the device, which are reported to the FDA. Ebnet Decl. Ex. E at 99:5.

Finally, with respect to the allegation that Mayo "blocked its own doctors from publishing a case report that would allow others to be aware of this potential issue," Pl. Br. 24, Plaintiff offers no facts about the case report in question or how it may have related to what Plaintiff regards as the "potential issue." And Plaintiff fails to explain how Dr. Villavicencio's inclination not to publish a particular case report or article—which neither he nor Mayo has any legal obligation to do—amounts to supposed "concealment" of any meaningful information.

ARGUMENT

I. Standard of Review

"'In the Federal Courts of this District, the pleading of punitive damage claims, under causes of actions premised upon the law of the State of Minnesota, must generally conform to the requirements of Minnesota Statutes Sections 549.191 and 549.20.'" *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1008 (D. Minn. 2003) (quoting *Olson v. Snap Prods., Inc.*, 29 F. Supp. 2d 1027, 1034 (D. Minn. 1998)).[9]

[9] The judges of this District have recently expressed some disagreement regarding the interplay between Fed. R. Civ. P. 15 and the Minnesota Statutes. *Compare In re Bair Hugger*, 2017 U.S. Dist. LEXIS 193938 at *10 (denying motion to amend to claim punitive damages under Rule 15) *with Inline Packaging, LLC v. Graphic Packaging Int'l, LLC*, 2018 U.S. Dist. LEXIS 74102, at *93 (D. Minn. Mar. 8, 2018) (denying motion to amend under Minn. Stat. § 549.20).

Punitive damages are an "extraordinary sanction." *Lundgren v. Eustermann*, 370 N.W.2d 877, 882 (Minn. 1985). When punitive damages are injected into a case, "the defendant's reputation as well as his money become involved, and the litigation can assume a different dimension." *Id.* Thus, the Minnesota Supreme Court has cautioned that the "very power of the remedy demands that judges exercise close control over the imposition and assessment of punitive damages." *Id.* (cleaned up); *see also Lewis v. The Equitable Life Assurance Soc.*, 389 N.W.2d 876, 892 (Minn. 1986) (punitive damages are disfavored, and allowed only "with caution and within narrow limits.").

Recognizing the extreme nature of the remedy, the Minnesota Legislature has enacted three specific directives "to limit the frequency and amounts of punitive damages awards." *Minnesota-Iowa Television Co. v. Watonwan T.V. Improvements Ass'n*, 294 N.W.2d 297, 311 (Minn. 1980); *see also Gamma-10 Plastics, Inc. v. Am. President Lines, Ltd.*, 32 F.3d 1244, 1255 (8th Cir. 1994) (describing legislature's aim "to prevent frivolous punitive damages claims by allowing a court to determine first if punitive damages are appropriate.").

First, Minn. Stat. § 549.191 prohibits a plaintiff from seeking punitive damages at the outset of a civil action, requiring instead that the plaintiff seek

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Plaintiff cites the Minnesota Statutes and not Fed. R. Civ. P. 15 or the plausibility standard, *see* Pl. Mem. 25-26, so Mayo responds to Plaintiff's arguments under the Minnesota statutory standard. If this Court concludes that Rule 15 governs, Plaintiff's motion must be denied because Plaintiff has not supplied the Court with a proposed amended pleading, *see Daniel v. Honeywell Int'l Inc.*, 2023 U.S. Dist. LEXIS 176672, at *15-*17 (D. Minn. Oct. 2, 2023) (denying motion to amend for failure to comply with Local Rule 15.1), and because the factual averments in Plaintiff's Complaint do not satisfy the deliberate disregard standard, *see* ECF 1 ¶¶ 1-17.

leave of court to add a punitive damages claim by presenting "prima facie evidence in support of the motion." Minn. Stat. § 549.191. Prima facie evidence means evidence which, if unrebutted, would support a judgment in the moving party's favor. *Swanlund v. Shimano Industrial Corp.*, 459 N.W.2d 151, 154 (Minn. Ct. App. 1990). The term refers to "a procedure for screening out unmeritorious claims for punitive damages." *Id.*

Second, Minnesota law imposes a high substantive standard for punitive damages. In 1990, the Minnesota Legislature elevated the standard from "willful indifference" to "deliberate disregard." *See Bougie v. Sibley Manor, Inc.*, 504 N.W.2d 493, 500 n.4 (Minn. Ct. App. 1993). Under this standard, punitive damages are allowed only upon clear and convincing evidence that the defendant acted with "deliberate disregard for the rights or safety of others." Minn. Stat. § 549.20, subd. 1(a).

The phrase "deliberate disregard" is defined by statute:

> (b) A defendant has acted with deliberate disregard for the rights or safety of others if the defendant has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others and:
>
> > (1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or
> >
> > (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.

Id., subd. 1(b). This heightened standard requires evidence of "egregious" misconduct, *Lundgren*, 370 N.W.2d at 882, such as "maliciousness, an intentional or willful failure to inform or act." *Beniek v. Textron, Inc.*, 479 N.W.2d 719, 723

(Minn. Ct. App. 1991). Mere negligence, or even gross negligence, is insufficient as a matter of law to satisfy the "deliberate disregard" standard. *See Admiral Merchs. Motor Freight, Inc. v. O'Connor & Hannan*, 494 N.W.2d 261, 268 (Minn. 1992).

Third, Minnesota law further restricts punitive damages through an elevated burden of proof. A plaintiff must show by "clear and convincing evidence" that the defendant acted with deliberate disregard. Minn. Stat. § 549.20, subd. 1(a). This clear-and-convincing standard is met only if "it is highly probable that the defendant acted with deliberate disregard." *Freeland v. Fin. Recovery Servs., Inc.*, 790 F. Supp. 2d 991, 995 (D. Minn. 2011) (internal quotation marks omitted).

Plaintiff suggests the prima facie threshold for her motion is less demanding than the ultimate burden of clear and convincing proof. Pl. Mem. 26. But it is well settled that clear and convincing evidence "is implicitly incorporated into the requirement that the movant present a prima facie case" of deliberate disregard. *See, e.g.*, *Swanlund*, 459 N.W.2d at 154. Thus, Plaintiff must establish even her prima facie case by clear and convincing evidence. *See Healy v. I'Flow, LLC*, 853 F. Supp. 2d 868, 875 (D. Minn. 2012); *Berczyk*, 291 F. Supp. 2d at 1013-14 (noting with "more than passing dismay" that plaintiffs "woefully misunderstood their burdens under Sections 549.191 and .20" when they argued the clear-and-convincing standard did not apply to a motion to amend to add punitive damages).

Moreover, in the Court's assessment of Plaintiff's motion, Plaintiff is not entitled to the benefit of all reasonable inferences. At "summary judgment all

factual disputes are taken in a light most favorable to the non-movant whereas to amend for punitive damages no such deference is given to the asserted facts." *Cenveo Corp. v. S. Graphic Sys.*, 2011 U.S. Dist. LEXIS 71962, at *1-*2 (D. Minn. July 1, 2011). The "function of the trial court is to do more than 'rubber stamp' the allegations in the motion papers." *Shetka v. Kueppers, Kueppers, Von Feldt & Salmen*, 454 N.W.2d 916, 918 n.1 (Minn. 1990). Rather, the Court must independently ascertain whether there exists prima facie evidence that Mayo acted with deliberate disregard. *Ulrich v. City of Crosby*, 848 F. Supp. 861, 868-69 (D. Minn. 1994). In making this determination, the Court should ignore "argument dressed up as factual averment" and Plaintiff's characterization of evidence and conclusory statements, which do not constitute evidence. *Stepnes v. Ritschel*, 2010 U.S. Dist. LEXIS 143497, at *18 n.3 (D. Minn. Apr. 13, 2010).

Finally, the Court must consider the record as a whole to ensure the evidence is presented in its proper context. *Id.* at *21 n.4; *see also* 27 Minnesota Practice § 13.19 (2009) ("To the extent that the plaintiff has submitted only a portion of deposition testimony and documentary evidence relevant to his claim for punitive damages, the court should consider the full evidentiary record in determining whether the plaintiff has met his burden of providing a prima facie case of entitlement to punitive damages.").

II. The Court Should Deny's Plaintiff's Motion Because Plaintiff Lacks Prima Facie Evidence to Support Essential Elements of Her Claims

The Court should deny Plaintiff's motion at the threshold because her evidence fails to establish necessary elements of her causes of action, even on a prima facie basis. As a matter of law, any claim for punitive damages fails if the underlying claim fails. "Punitive damages are a derivative claim like loss of

consortium," *Bergman v. Johnson & Johnson*,, 2021 U.S. Dist. LEXIS 152758, at *17 (D. Minn. Aug. 13, 2021), and thus if the underlying claim fails, so too does the derivative claim. *See Kiminski v. American Family Mut. Ins. Co.*, 1993 Minn. App. LEXIS 1147, at *2-*3 (Minn. Ct. App. Nov. 23, 1993); *see also Hern v. Bankers Life Cas. Co.*, 133 F. Supp. 2d 1130, 1136 (D. Minn. 2001) (same).

A. Plaintiff Has Not Proffered Any Expert Testimony Regarding Applicable Standards of Care

There can be no dispute that each of Plaintiff's underlying causes of action in this case—medical negligence, negligent nondisclosure, and medical battery—requires supporting expert testimony in order to be submissible to a jury. *See, e.g., Haile v. Sutherland*, 598 N.W.2d 424, 427-28 (Minn. Ct. App. 1999) (expert testimony required to support medical negligence and medical battery claims); *Reinhardt v. Colton*, 337 N.W.2d 88, 96 (Minn. 1983) (expert testimony required to support claim for negligent nondisclosure).

If Plaintiff cannot make a case even for compensatory damages without expert testimony to support the essential elements of her claims, *a fortiori* she cannot seek punitive damages without that necessary evidentiary support. As explained above, Plaintiff's burden on this motion is to make a prima facie showing that Mayo acted with "deliberate disregard" for Leopold's "rights or safety." In this case involving extraordinarily complex medical practice, any analysis of the "rights" at issue, and any analysis of how Mayo's acts or omissions may have affected Leopold's safety, necessarily requires expert testimony—a lay jury cannot possibly assess whether Mayo acted improperly or outrageously without competent evidence to explain what reasonable physicians would do under similar circumstances.

The Court need not investigate further. Because Plaintiff has failed to supply the requisite expert testimony to support any of her claims, she cannot meet the standard to seek punitive damages. *Njema*, 2014 U.S. Dist. LEXIS 206126 at *36-*37.

B. Plaintiff Fails to Plausibly Allege or Support Causation With Expert Testimony

Plaintiff's claims, and her motion for punitive damages, also fail for the independent reason that Plaintiff does not offer expert testimony—and in fact does not even allege any facts or proffer any evidence—plausibly suggesting a causal connection between Mayo's alleged acts or omissions and the complication Leopold experienced in surgery, the cause of which remains unknown, as explained above. These defects are fatal to her motion.

Minnesota Statutes Section 549.20 requires (1) knowledge of or an intentional disregard of facts that make injury to a plaintiff's rights probable; and (2) action despite such knowledge. *In re Bair Hugger*, 2017 U.S. Dist. LEXIS 193938 at *21. In order for an injury to be probable, there must be a causal connection between the facts known or intentionally disregarded by defendant and plaintiff's alleged harm. *Id.*

In re Bair Hugger is instructive on this point. In that case, plaintiffs moved to add a claim for punitive damages on the theory that defendants knew a surgical device was contaminated with bacteria. *Id.* at *20-*22. However, the device at issue did not make contact with the surgical site, and the court declined to accept plaintiffs' conclusory statement that presence of bacteria in the device was equivalent to a patient safety risk, noting that "studies relied on by reference in the pleadings" disclaimed "any direct correlation between the presence of

bacteria and an increase in the risk of surgical site infections." *Id.* Hence, there was "no reasonable inference that could be drawn by a factfinder that presence of bacteria in the device would result in an increased infection risk of the surgical site itself. . . . [F]ailing to warn of bacterial contamination[] does not permit the reasonable inference that Defendants were deliberately indifferent to an increased risk of surgical site infections." *Id.* at *22-*23.

The same is true here. Plaintiff has not provided any evidence to establish a causal connection between Mayo's conduct and the injury to Leopold. Plaintiff's central argument is that Mayo failed to disclose several allegedly significant risks associated with the donor and with the use of the OCS Heart device. But Plaintiff has not cited one iota of evidence that *any* of those supposed risk factors—for example, the donor's history of tobacco use or his past incarceration—caused the August 29 Donor Heart to fail. As a result, even if the Court were to assume Mayo intentionally disregarded that information, Plaintiff has not established that Mayo's alleged actions constituted willful or reckless disregard of "a high probability of injury." Minn. Stat. § 549.20. The Court should deny Plaintiff's motion on this basis alone. *See Azbill v. Grande*, 2005 Minn. App. LEXIS 596, at *23 (Minn. Ct. App. June 7, 2005) ("Because [plaintiff] has failed to show causation as to her substantive claims, she cannot sustain her burden to show that a punitive-damage claim would also be warranted.").

Beyond the foregoing threshold failures, careful review of the law and evidence relevant to each of Plaintiff's arguments shows there is no factual basis for a punitive damages claim in this case. Mayo responds to Plaintiff's specific arguments in turn below.

III. Plaintiff's Nondisclosure Claims Do Not Support Punitive Damages

A. Plaintiff Fails to Proffer Evidence Meeting Reasonable Person Standard

As explained below, the Court's independent assessment of Plaintiff's evidence regarding Mayo's nondisclosure of various alleged risks to Leopold will show that this evidence falls woefully short of the high standard necessary to support a punitive damages claim. But Plaintiff's arguments premised on her negligent nondisclosure claim fail for an additional reason—they expressly rely on a subjective standard, rather than the objective, "reasonable person" standard that applies to Plaintiff's claim.[10]

In Minnesota, "[t]he existence of the duty [to disclose medical risks] depends on an objective standard: A duty to disclose arises if the doctor knows or should know of the risk." *Kinikin v. Heupel*, 305 N.W.2d 589, 595 (Minn. 1981). If there is a duty to disclose, the next question is what must be disclosed, i.e., the scope of disclosure. *Id.* This too is an objective standard. A physician must disclose those risks that skilled practitioners of good standing in the community would reveal, as well as those risks a "reasonable person" in "plaintiff's position would consider significant when contemplating surgery." *Id.*

The relevant CIVJIG incorporates these objective standards. A risk is significant if "[t]he physician knows or should know that a reasonable person in

[10] Plaintiff claims Mayo witnesses conceded that Leopold was entitled to any information he would consider significant, Pl. Mem. 27, but those witnesses made no concessions regarding what the law requires, nor could they. Thompson Decl. Ex. W at 60:21-22 (objecting to Plaintiff's counsel's questioning as calling for a legal conclusion). Instead, some witnesses merely agreed that they "strive" to give patients all relevant information, and further, that they believe they did so in this case. *Id.* Ex. T at 53:19-54:1; Ex. V at 29:24-30:5; Ex W at 60:23-25.

the patient's position would regard it as significant" or "[i]t is the type of risk that a [physician] customarily tells a patient about under similar circumstances." Minn. Prac. 4A, CIVJIG 80.25. Because these are objective standards, and as discussed *supra*, expert testimony is required to establish the existence of a relevant risk, that it is accepted medical practice for the physician to know of that risk, and that the undisclosed risk resulted in harm. *Clark v. Miller*, 378 N.W.2d 838, 845 (Minn. Ct. App. 1986).

Plaintiff's Complaint even recognizes the objective standard that applies to her nondisclosure claim, alleging that "[a] ***reasonable person*** in Mr. Leopold's position would not have consented to the procedure if the risks and alternatives outlined above had been appropriately disclosed." ECF 1 ¶ 27 (emphasis added).

Notwithstanding the above law and her own pleading, Plaintiff argues that Leopold's inquisitive nature required Mayo to inform him of even the "most mundane details" regarding the heart transplantation surgery, including "every aspect" of the donor and donor organ and "every aspect" of the surgery itself. Pl. Mem. 12, 27, 29. Plaintiff argues that Mayo's purported failure to inform Leopold of details he would have found significant is a basis for punitive damages.[11] *Id.* at 27-43. Plaintiff is wrong. *See Cannon v. Lucas-Silvis*, 2011 Minn. Dist. LEXIS 54, at *10-*11 (Minn. Dist. Ct. Mar. 25, 2011) (denying motion for judgment as a matter

[11] Contrary to Plaintiff's argument, Pl. Mem. 27, Minnesota's "Patient Bill of Rights" is irrelevant to the Court's analysis; it does not alter the reasonable person standard, nor does it confer a private cause of action that may serve as an independent basis for punitive damages. *See, e.g.*, *Smith v. Children's Minn.*, 2020 Minn. Dist. LEXIS 184, at *16-*17 (Minn. Dist. Ct. Jan. 6, 2020) (dismissing claim that defendants violated Patient Bill of Rights because "no private right of action exists under the statute").

of law because "it is not the subjective preference of [plaintiff] which applies to [p]laintiff's informed consent claim, but rather the objective test of [] a reasonable person in [p]laintiff's position"). Indeed, Plaintiff has failed to supply the court with any evidence that the information Plaintiff believes should have been disclosed—e.g., the donor's drug and other social history (Pl. Mem. 29-31), the donor's mechanism of death (*id.* at 31-32), the device used to preserve the donor heart during transport (*id.* at 32-33), or the timing of explantation of Leopold's native heart (*id.* at 34-35)—were (1) factors that were known or should have been known to increase the risk of Leopold's heart transplantation surgery; and (2) information disclosed by skilled practitioners of good standing in the community, or (3) risks a "reasonable person" would consider significant. *Kinikin*, 305 N.W.2d at 595.

In the absence of such evidence, the Court cannot conclude that Leopold had a legally cognizable "right" to the information his family now claims he should have been informed of. Therefore, Plaintiff has failed to sustain her burden to make even a prima facie case, by "clear and convincing evidence," that Mayo "deliberately disregarded" a right that is, at best, uncertain to exist. *See Hern*, 133 F. Supp. 2d at 1136; *see also Hanson v. Friends of Minn. Sinfonia*, 2004 Minn. App. LEXIS 645, at *29 (Minn. Ct. App. June 8, 2004) (affirming denial of motion to add punitive damages claim because "appellant has not established a prima facie case for any of her claims").

In fact, the only relevant evidence on the objective standard is the testimony of Mayo's physicians; they are in agreement that Leopold was provided all clinically relevant information regarding the surgery he consented

to. *See, e.g.*, Thompson Decl. Ex. W at 72:13, 79:7 (disagreeing with counsel's assertion that a patient is entitled to all information that might be significant to them; instead, Mayo discloses information that is "clinically relevant" and "significant to the outcome"); Ex. T at 137:10-23.

B. Plaintiff's Allegations Regarding the Donor's History Do Not Support Punitive Damages

Plaintiff seeks to support her claim for punitive damages on the ground that Mayo supposedly "deliberately deprived" Leopold of information about the donor's history, including his mechanism of death. *See* Pl. Mem. 29-32.

The Court should reject this argument at the threshold, because Plaintiff's own allegations make clear that Leopold knowingly consented to proceed with transplantation surgery—not once, but twice—after Mayo expressly informed him that he could not receive information about the donor's history. *See supra* pp. 6-9. Norman Leopold alleges that in preparing for the August 17 transplantation surgery that was subsequently deferred, Leopold asked Dr. Spencer "many questions . . . regarding the donor," including questions "about the donor's medical history, drug use, age, and location." ECF 32 ¶ 6. In response, "***Dr. Spencer said he was not allowed to disclose any such information***." *Id.* (emphasis added). Leopold consented anyway, and he consented again on August 29, having been told expressly that Mayo would not disclose information about the donor's history.

Thus, according to Plaintiff's own allegations, Mayo did not "conceal" anything from Leopold—Mayo forthrightly told Leopold it could not disclose certain information about the donor. Having been fully informed of that limitation, Leopold chose to proceed to anyway. These facts cannot support a

claim for negligent nondisclosure in the first instance, much less a claim for punitive damages.

Further, Plaintiff fails to adduce any evidence—which would necessarily require expert testimony as explained above—to support her naked allegations that various facts about the donor's history were material to Leopold's care.[12] For example, Plaintiff seems to believe it was outrageous for the Mayo physicians not to disclose to Leopold that the donor had a history of tobacco and drug use. But the only competent medical evidence in the record comes from the Mayo physicians, and they have testified that this information was not clinically relevant to Leopold's situation. *E.g.,* Thompson Decl. Ex. W at 77:23-78:3 ("[Y]es, the patient may have used methamphetamine; yes, the patient may have used tobacco; yes, they might have used alcohol. But if the heart is good, it's good. And the heart is looked at pretty rigorously before it's taken.").

Plaintiff cites a paper written by Dr. Villavicencio regarding outcomes of hearts from donors who died of intracranial hemorrhage. Pl. Mem. 31-32. But Dr. Villavicencio testified that this study confirmed that hearts from such donors are routinely transplanted across the country, and that the "one percent difference" in survival rates found in this study may have resulted from other factors and is "[n]ot clinically significant." *Id.* Ex. T at 43:8-44:5.

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[12] To the extent Plaintiff bases her claims on Leopold's alleged reliance on Dr. Ternus's reassurance that the Mayo transplant team wanted to find Leopold a "perfect" heart, the claims fail. Viewed in context, no reasonable person could possibly interpret this statement as a promise or guarantee of literal perfection. As a matter of law, such statements cannot support a claim sounding in misrepresentation or nondisclosure, much less punitive damages. *See, e.g., Anderson v. 1399557 Ont. Ltd.*, 2019 U.S. Dist. LEXIS 190608, at *19 (D. Minn. Nov. 4, 2019).

[redacted] Plaintiff's contention that Mayo physicians should have counseled Leopold about an imagined medical history they had already confirmed was inaccurate is facially absurd and cannot support a claim for punitive damages.

C. Mayo's Reliance on OPTN Guidance Defeats Any Claim for Punitive Damages

Mayo's compliance with guidance from the Organ Procurement and Transplantation Network ("OPTN"), noted in Plaintiff's motion, further undermines her claim for punitive damages. Established by Congress in 1984, OPTN is a public-private partnership that serves to link all professionals involved in the United States donation and transplantation system.[13] In recognition of the importance of "maintaining appropriate confidentiality protections," OPTN establishes guidance for transplant centers' sharing of information with donors and recipients ("OPTN Guidance"). Thompson Decl. Ex. S at 1. The OPTN Guidance states that any information regarding a donor that is shared with a recipient should be "limited to information required as part of the recipient informed consent process" and "non-identifiable and general" so as to "never make it possible to identify the donor." *Id.* at 2. Shared information should not include "geography information" "specific diagnosis," "chronic illness unrelated to the donation," and "mechanism of injury or death." *Id.*

[13] https://optn.transplant.hrsa.gov/about/history-nota/.

Mayo's clinical practices in regard to informed consent are a good-faith implementation of the OPTN Guidance, and an independent basis to reject Plaintiff's claim for punitive damages based on nondisclosure about the donor's history. As the foregoing makes clear, the OPTN Guidance establishes generally that donor information shared with recipients should be *limited*, and specifically advises against disclosure of particular categories of information, including information Plaintiff focuses on in her motion, such as the donor's mechanism of death. The Mayo physicians testified that their disclosures to Leopold were made in accordance with this guidance, which is consistent with practice in the field generally. *E.g., id.* Ex. V at 95:22-96:22 (noting that physicians face "conflicting" duties to recipients and donors in light of the need to protect donor confidentiality per the OPTN Guidance); Ex. T at 129: 8-130:19 (testifying the OPTN Guidance meant "I cannot disclose" the "mechanism of this donor's death").

Plaintiff argues that the OPTN Guidance is inconsistent with Minnesota law, or that the Mayo team misapplied it, but Plaintiff misses the point. Plaintiff may disagree with the OPTN Guidance of Mayo's implementation of it, but Plaintiff cannot dispute that the OPTN Guidance provides an objective basis for Mayo's approach to these issues, on which the Mayo physicians relied in good faith. This conclusively shows the Mayo team did not act with "deliberate disregard" of Leopold's alleged right to receive certain information. Rather, they believed in good faith that the principles in the OPTN Guidance prevented disclosure of certain information. This defeats any potential claim for punitive damages. *See, e.g., Roworth v. Minn. Mut. Life Ins. Co.*, 674 F.2d 756, 758 (8th Cir.

1982) (good faith is a defense to punitive damages, even where a defendant is mistaken in its belief that its actions were legally correct); *Peterson v. Sorlien*, 299 N.W.2d 123, 129-30 (Minn. 1980).

D. Plaintiff's Allegations Regarding the OCS Device Do Not Support Punitive Damages

Plaintiff argues that Mayo should be liable for punitive damages because it did not disclose to Leopold supposed "risks" associated with using the OCS Heart device. Pl. Mem. 32-33. Plaintiff's argument fails.

Plaintiff does not and cannot dispute that Mayo used this FDA-approved device for exactly the indication for which it is approved. And as detailed above, Plaintiff's claims about these supposed "risks" are misguided at best and fabricated worst—they are premised on misinterpretation or misrepresentation of the findings of 10-year-old clinical research. *Supra* pp. 17-21. And there is no competent medical evidence that the OCS device caused Leopold's complication. All that remains is disagreement between the parties regarding medical literature and manufacturer guidelines, neither of which can support a claim for punitive damages. *See, e.g.*, *Thone v. Reg'l West Med. Ctr.*, 745 N.W.2d 898, 905-06 (Neb. 2008) (recognizing that "highly complex" medical decisions like "treating and diagnosing a patient . . . should not be scrutinized according to a rigid set of black-letter instructions" from a manufacturer's guidelines, especially without the aid of expert testimony).

IV. Plaintiff's Allegations Regarding Mayo's Procurement and Monitoring of the August 29 Donor Heart Do Not Support Punitive Damages

Plaintiff contends that Mayo should be liable for punitive damages because the surgeons who procured the August 29 Donor Heart slept on the

return flight to Mayo, and because the Mayo perfusionist supposedly saw "warning signs of deteriorating cardiac function and did not inform the transplant doctors." Pl. Mem. 47-48. But the evidence confirms these purported "concerns" are no more than Plaintiff's fabrications.

Danielle Fay, the Mayo perfusionist in question, testified that it is entirely normal and appropriate for the surgeons to sleep periodically on procurement flights. Thompson Decl. Ex. Z at 37:21-22; 123:4-20. Continuous monitoring of the OCS device is the role of the perfusionist—not the surgeons—and the surgeons are immediately available if problems occur. *Id.*

As to supposed "warning signs of deteriorating cardiac function," there were none, as explained above. *Supra* pp. 15-17. Plaintiff simply misquotes Ms. Fay's text messages and misrepresents her unequivocal sworn testimony: "I feel that everything from that [procurement] run, from the time we got [the August 29 Donor Heart] on [the OCS device] to the time it came off, it looked good. I had no concerns." Thompson Decl. Ex. Z at 123:16-18. Ms. Fay did not report any concerns to the transplants surgeons because there were no concerns to report.

V. Plaintiff's Allegations Regarding Surgical Technique Do Not Support Punitive Damages

Plaintiff seeks to base a punitive damages claim on the allegation that while Dr. Spencer told Leopold that his "heart would not be explanted until the donor's heart was examined in the OR and confirmed to be suitable for transplant," Pl. Mem. 15, Dr. Villavicencio, who performed the August 29 surgery, began to explant Leopold's native heart before the donor heart arrived in the operating room. Pl. Mem. 34, 38-50. But Plaintiff fails to adduce the required clear and convincing prima facie evidence in support of this claim.

Dr. Villavicencio explained in deposition that his practice is to time the steps in the surgical procedure so that the recipient's native heart is explanted when the donor heart arrives in the operating room, so that the donor heart can be implanted without delay. Thompson Decl. Ex. T at 28:7-20. The reason for this approach is to "minimize the time on the OCS to minimize the time of the heart out of the body," which leads to better clinical outcomes for patients. *Id.* at 29:18-20; 29:5-8; 37:14-18. To ensure the donor heart remains suitable for transplantation after its transit to Mayo, however, Dr. Villavicencio typically waits for the procurement team to confirm the donor heart's status after landing at the airport in Rochester, then begins steps to explant the native heart after receiving that confirmation. *Id.* at 28:10-20.

Plaintiff's allegations about this issue fail to establish a basis for punitive damages for several reasons. First, Plaintiff does not even allege that Dr. Villavicencio made any representations to Leopold about this aspect of the surgical procedure. Her allegation that a *different surgeon*—Dr. Spencer—supposedly outlined a different approach cannot support a claim that Dr. Villavicencio misled Leopold about the surgical technique.

Second, Plaintiff's allegations fall far short of clear and convincing evidence that anyone at Mayo promised Leopold that the surgical team would not begin explanting his native heart before the donor heart arrived in the operating room. The only evidence of what Dr. Spencer supposedly told Leopold comes from allegations by Plaintiff's family. Plaintiff's professed surprise notwithstanding, the medical literature Plaintiff cites makes clear that Dr. Villavicencio's approach is actually typical, stating the "surgeon always has to

wait ***for the donor heart to land in the vicinity of the recipient hospital*** before performing any irreversible step of explanting the native heart." *Id.* Ex. Q at 5-6 (emphasis added). Similarly, Karen Leopold's text message allegedly sent after the conversation with Dr. Spencer is perfectly consistent with Dr. Villavicencio's approach. Contrary to Plaintiff's assertion, it *does not* say Dr. Spencer promised the donor heart would be inspected in the operating room before explantation of the native heart. It actually says the surgical "team will reconfirm it is suitable before they proceed with the transplant." *Id.* Ex. R. That is exactly what happened in this case – the procurement surgeons, who are part of the "team," confirmed the suitability of the heart before Dr. Villavicencio proceeded. *See id.* Ex. T at 28:10-20.

Plaintiff also alleges that Mayo should be liable for punitive damages because Dr. Villavicencio did not perform a predicted heart mass calculation for the August 29 Donor Heart using an online calculator. Pl. Mem. 45-46. But as explained above, Dr. Villavicencio testified that he does not rely on this tool, and considers other relevant factors in assessing the expected size of the donor heart. *Supra* p. 7-8.

All of Plaintiff's arguments regarding surgical technique simply underscore Plaintiff's critical failure to adduce any expert testimony in support of her claims or her motion. Absent expert testimony, a lay jury could not possibly decide that Mayo acted negligently—much less with deliberate disregard—in relation to these complex issues of transplant medicine and surgery. *See, e.g., Haile*, 598 N.W.2d at 428 (holding "expert testimony is crucial to understanding whether respondents breached their responsibilities during

surgery or deviated from the steps necessary to assure the correct procedure was performed").

VI. Plaintiff Fails to Identify Any Case Law Permitting a Claim for Punitive Damages on Comparable Facts

The six trial court orders cited by Plaintiff provide no support for her motion, as each of them is readily distinguishable on the facts.

For example, *Vasquez-Sierra v. Hennepin Faculty Associates, et al.*, No. 27-CV-12-1611 (Henn. Cty., December 14, 2012), involved a surgeon who took "no action" and "ignored" evidence that a medical procedure had been unsuccessful, and then did not speak to the patient about the issue. *Id.* FF ¶¶ 9-10, CL ¶¶ 8-12. The surgeon's actions and inactions were contrary to the undisputed and objective "standard practice" at the medical facility where the procedure was performed. *Id.* FF ¶ 5. The judge's order expressly relied on "the undisputed fact that the surgeon received a pathology report that provided empirical evidence [that the surgery was a failure] and [the surgeon] decided to ignore it completely." *Id.* CL ¶ 11. The decision did not rely on or consider plaintiff's subjective preferences.

Similarly, *Turner v. Multicare Associates, et al.*, No. C8-95-14938 (Anoka Cty., July 25, 1996), involved a doctor's initial assurance to a patient that her chest x-rays appeared normal, followed by his subsequent discovery of an abnormality that required follow-up. Importantly, the doctor "knew that the abnormality . . . could lead to cancer and be fatal." *Id.* at 10. In other word, there was objective evidence that the information at issue was appreciated as significant by defendant and should have been disclosed. *Id.* Here, by contrast, Leopold was

provided with all the information that Mayo's providers deemed clinically relevant. *Supra* pp. 9, 13-15.

Plaintiff's other citations are even less apposite. *Bednar v. Poland*, No. C6-02-1128 (Crow Wing Cty., May 5, 2003), involved a doctor who deliberately altered a patient's chart after a surgery had gone wrong in an effort to exculpate the doctor's conduct. *Id.* at 2-5. *Bartlett v. Cox-Marinelli*, No. 27-CV-06-194 (Henn. Cty., October 11, 2006), involved a doctor who performed a surgery despite suffering from serious illness; the doctor had a financial incentive to do so. *Morrissey v. Wilkinson, et al.*, No. C7-98-03461 (Ramsey Cty., December 11, 1998), involved health care providers that held themselves out as possessing specialized knowledge to care for a particular patient population, but in reality they had never treated such patients and had no relevant formal training or education. *Id.* at 5. Finally, *Lingren v. Pinnacle Recover Services PSC, et al.*, No. 09-CV-13-215 (Carlton Cty., Sept. 22, 2015), involved doctors who frequently violated federal regulations regarding the prescription of methadone. *Id.* at 11-15.

None of the six cases cited by Plaintiff supports Plaintiff's allegations that Mayo deliberately disregarded Leopold's rights or safety. Plaintiff fails to cite any cases permitting punitive damages on comparable facts because there are none. This is not a punitive damages case.

CONCLUSION

For all the foregoing reasons, the Court should deny Plaintiff's motion to add a claim for punitive damages.

Dated: October 8, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Michelle Simha, as Trustee for the Next-of-Kin of Noah Leopold, Plaintiff, vs. Mayo Clinic, Defendant.	Civil File No. 24-CV-01097-DTS **MAYO CLINIC'S WORD COUNT COMPLIANCE CERTIFICATE**

I, Nathan J. Ebnet, certify that Defendant Mayo Clinic's Memorandum in Opposition to Plaintiff's Motion to Amend to Add a Claim for Punitive Damages complies with Local Rules 7.1(f) and 7.1(h).

I further certify that, in preparation of the Memorandum, I used Microsoft Word and that the word count function of this word processing program has been applied specifically to include all text, including headings, footnotes and quotations, in the following word count. I further certify that the above-referenced Memorandum contains 11,877 words.

I further certify that the above-referenced Memorandum complies with the type-size requirements of Local Rule 7.1(h) because it has been prepared using 13-point Book Antigua type as designated by Microsoft Word.

Dated: October 8, 2024

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